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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,804	03/22/2004	David C. Baulcombe	616292000111	9959

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MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER
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MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/805,804	BAULCOMBE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 116-124 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 116-124 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/491,549.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07022007; 07262007; 09/10/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The amendment filed November 8, 2007 was entered.
3. The objection to claim 119 is withdrawn in light of its amendment.
4. The rejection of claims 116-124 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn in light of the claim amendments.
5. The rejection of claims 116-124 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, as failing to comply with the enablement requirement is withdrawn upon further consideration.

### ***Specification***

6. The abstract remains objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, for the reasons of record stated in the Office action mailed June 26, 2007. Applicants traverse in the papers filed November 8, 2007. Applicant's arguments have been fully considered but were not persuasive.

Applicants assert that they were unable to find a copy of the abstract filed March 17, 2006 either in their own file or in the file history on Public PAIR, but that if the presently

proposed abstract is satisfactory, this is not an issue (response, page 5, 1<sup>st</sup> full paragraph). The abstract states, "SRMs consist essentially of short sense RNA molecules and short antisense RNA molecules". Written descriptive support is lacking for "consist essentially of". The specification does not describe SRMs to "consist essentially of" SSRMs and SARMs, but rather describes SRMs as being SSRMs or SARMs. Page 2, lines 22-23 of the specification states, "...such short sense and antisense RNA molecules (hereinafter, collectively SRMs)". Page 4, lines 20-25 states, "In performing the invention, it may be preferred to analyse or otherwise utilise short anti-sense RNA molecules (SARMs) rather than short sense RNA molecules (SSRMs). Nonetheless, where reference is made herein to SARMs (except where context clearly suggests otherwise) it will be appreciated by those skilled in the art that the SSRMs may also be used." The specification describes SRMs as SARMs or SSRMs, but does not describe what else SRMs "consist essentially of". The recitation, "consist essentially of" is NEW MATTER and must be deleted. It is suggested that the recitation be replaced with --are--.

Note: the abstract filed by Applicants on March 17, 2006 is dated March 21, 2006 in Public PAIR.

***Claim Rejections - 35 USC § 112***

7. Claims 116-124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 26, 2007. Applicants

traverse in the papers filed November 8, 2007. Applicant's arguments have been fully considered but were not persuasive.

The rejection in the previous Office action indicated that the phrase "comprise" was new matter. Applicants argue that this objection is obviated by substitution with "consist essentially of" (response, page 6, 1<sup>st</sup> full paragraph). However, written description support is lacking in the specification for this recitation as well, and is also NEW MATTER. It is suggested that in claim 116 this recitation be replaced with --are--, and in claim 120 the recitation, "consist essentially" be deleted.

Applicants argue that claims to a genus need not disclose every member of that genus or even demonstrate any particular species was contemplated. Applicants cite *Amgen, Inc. v. Hoeschst, Marion Roussel*, 314 F3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003) in support and assert that this case is precisely on point, and that there is no need for the applicant to contemplate every species that falls within a claimed genus in order to provide adequate written support (response, page 6, 2<sup>nd</sup> full paragraph to page 7, 1<sup>st</sup> full paragraph). However, here, Applicants have in their written responses contemplated double-stranded RNA species to be within the scope of the claims. Further, in *Amgen, Inc. v. Hoeschst, Marion Roussel*, the court asserted that they presumed that if the examiner thought the specification taught only the use of exogenous DNA, the asserted claims would not have issued, and that TKT (the accused infringer in that decision) did not direct the court's attention to anything in the intrinsic record that rebuts the presumption that the plain meaning of the terms controls. The court therefore concluded that the scope of the asserted claims should not be limited to the expression of exogenous DNA (page

1326). In the instant case, however, the Examiner has raised the issue that the introduction of double-stranded short RNA molecules into cells is not supported by the specification.

Applicants next argue that the specification provides a description of dsRNA as one form in which the short RNA molecules could be utilized, even if the description was not explicit, as evidenced by the statement that SRMs refer collectively to SSRMs and SARMs; the definition of the nature of molecules as “short complementary molecules which could base pair with the target RNAs; the statement that the discovery of SRMs of the invention provides evidence that dsRNA induction of silencing in nematodes and the cause of PTGS in plants are related; and the statement that whenever a previously characterized species of antisense RNA complementary to targeted mRNA was detected “corresponding sense RNA molecules were also detected” (response, paragraph bridging pages 7-8). Each of these arguments were presented before by Applicants and addressed by the Examiner in previous actions, and will not be repeated here.

Applicants also submit a declaration under 37 CFR 1.132 signed by co-inventor Dr. David Baulcombe. Applicants argue that the declaration clarifies that the transgene silencing experiment described on page 24, lines 4-28 had to result in the production of double-stranded species active in inducing silencing (response, paragraph bridging pages 7-8). The declaration in item 2 discusses the experiment on page 24 of the specification, and indicates that an approximately 25 nucleotide GUS antisense RNA was detected in two of three tobacco cell lines carrying GUS transgene; that neither the 25-nucleotide GUS RNA nor PTGS was detected in the third cell line, which contained a transgene suppressor of the promoter associated with the GUS coding sequence, and the GUS coding sequence was not transcribed. Item 3 of the declaration addresses a statement on page 27 of the specification regarding the dependence of the 25

nucleotide GUS antisense RNA accumulation on sense transcription of GUS, that it is not possible to distinguish from the results whether the antisense RNA is made directly as a 25 nucleotide species or as longer molecules that are then processed. The declaration asserts that because the sense strand of the GUS RNA must be used as a template for production of the antisense RNA, that the sense and antisense RNAs involved in PTGS must be substantially complementary. In item 4, Dr. Baulcombe states that he believes the only way to interpret the results of the experiment on page 24 is that it demonstrates that small antisense RNA must be complementary to a sense strand. That the specification in the experiment on page 24 describes that the short antisense RNA molecule is complementary to a region in the target GUS mRNA is not in dispute. However, the specification as filed does not clearly describe that the short sense RNA molecules are double-stranded.

In support of the argument that species not explicitly described can be included in a generic claim, Applicants point to *In re Jones*, 958 F2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) (response, page 8, 1<sup>st</sup> full paragraph). However, that decision concerned an obviousness prior art rejection, not written description.

Applicants' arguments were confusing. On the one hand, Applicants argued that the specification provides a description of dsRNA as being one form in which short RNA molecules could be utilized, but on the other that the specification need not contain such a description. It may be worthwhile to reiterate here that the current form of this rejection concerns the matter of the recitation "consisting essentially of" as being NEW MATTER. It is again suggested that claim 116 be amended by replacing this recitation with --are--, and by deleting the recitation, "consist essentially" in claim 120.

***Claim Rejections - 35 USC § 102***

8. Claims 116-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (U.S. Patent No. 6,506,559), for the reasons of record stated in the Office action mailed June 26, 2007. Applicants traverse in the papers filed November 8, 2007. Applicant's arguments have been fully considered but were not persuasive.

Applicants argue that the Office action misinterprets Fire, and is inconsistent with the characterization of the work on Fire as set forth on page 7 of the action, which indicated that the references cited in the instant specification in support of induction of PTGS with dsRNA, teach induction with dsRNAs that are much longer than 20-30 base pairs in length (response, page 12, 1st full paragraph). However, the instant specification does not mention U.S. Patent No. 6,506,559. Therefore, obviously, the statement on page 7 of the previous Office action did not encompass '559. Applicants argue there is nothing in Fire that describes using short RNA molecules to effect gene silencing, that the only reference to 25 bases is in column 8. Applicants argue that the reference in column 8 does not refer to the length of the RNA molecules supplied, but to the length of the nucleotide sequence of the longer dsRNA that is required to be identical. Applicants argue that from Table 1 in '559, that much longer RNA molecules are employed (response, page 12, 2<sup>nd</sup> full paragraph and the paragraph bridging pages 12-13). However, there is nothing in '559 to indicate that the RNA sequence that is identical to the target gene sequence must only appear within a larger RNA strand. Further, column 8 is not the only reference to 25 bases in '559. Claim 10 also recites that the first ribonucleotide sequence comprises at least 25



bases which correspond to the target gene, and the second ribonucleotide sequence comprises at least 25 bases which are complementary to the nucleotide sequence of the target gene.

### ***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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January 28, 2008



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Art Unit 1638